



FOR IMMEDIATE RELEASE:

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## **U.S. DISTRICT JUDGE RULES IN FAVOR OF FRANCK'S PHARMACY IN LANDMARK PHARMACEUTICAL COMPOUNDING CASE**

On Monday, Judge Timothy J. Corrigan of the U.S. District Court for the Middle District of Florida ruled in favor of Franck's Pharmacy and held that the United States Food and Drug Administration (FDA) lacked the authority "to enjoin the long-standing, widespread, state-regulated practice of pharmacists filling a veterinarian's prescription for a non food-producing animal by compounding from bulk substances." *United States v. Franck's Lab, Inc.*, No. 5:10-cv-00147, slip op. at 79-80 (M.D. Fla. Sept. 12, 2011).

In April 2010, the FDA filed a highly publicized complaint seeking to enjoin Franck's veterinary compounding practice based on the novel legal theory that animal medications compounded from bulk ingredients constitute "new animal drugs" that cannot be distributed without an FDA-approved new animal drug application. The case was of national importance in that the FDA stated that Franck's Lab, Inc. – and all other pharmacists involved in compounding veterinary preparations with Active Pharmaceutical Ingredients – were in direct violation of Animal Medicinal Use Clarification Act, the FDA's Compliance Policy Guide, and the Food Drug and Cosmetic Act because those preparations are "new drugs" and subject to FDA review and approval. Franck's argued that the traditional, state-licensed pharmacy practice of compounding commercially unavailable veterinary medications when prescribed by a Veterinary Doctor from bulk ingredients is lawful.

At no time, as the government's complaint makes clear, did the government make any allegations, or even intimations of allegations, as to the quality of Franck's compounding practices.

In an 80-page decision, Judge Corrigan explained that "[t]he undisputed evidence [that the practice of compounding animal medication from bulk ingredients is an essential component of veterinary medicine] shows that allowing the FDA to enjoin a pharmacist's traditional, state-authorized practice of bulk compounding of animal drugs could destabilize the pharmacy profession and leave many animal patients without necessary medication." *Id.* at 75.

"Veterinary compounding is a longstanding, recognized and medically vital service," said Paul Franck, owner of Franck's Compounding Lab. "We have been compounding human and veterinary drugs for more than 28 years and we are as committed as ever to meeting the special needs of doctors, veterinarians and their patients."

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## About FRANCK'S COMPOUNDING LAB

Franck's Compounding Lab is a state of the art facility located in the heart of Central Florida serving clients nationwide. Compounding is the art of preparing customized medications. The lab, using pure chemicals, exceeds USP Chapter 797 guidelines for sterile compounding. We can provide our clients with medications in alternate dosage forms which are not commercially available.

The prescribed dosage is tailor made to meet the patient's specific needs, thereby maximizing therapeutic results. Flavored Powders, Pastes and Suspensions, Medicated Lollipops, Treats, Capsules, Lozenges and Rapid Dissolving Tablets are examples of the various dosage forms available.

Franck's is represented by Mark S. Brown, Jeffrey S. Bucholtz, Alan R. Dial, and Ashley C. Parrish of King & Spalding LLP. King and Spalding is located at 1700 Pennsylvania Avenue, Ste 300, Washington D.C. 20006.